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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,809

04/09/2004

Irving W. Wainer

1173-1025PUS2

9486

33883 7590 09/17/2008
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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

09/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,809	Applicant(s) WAINER ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9,11-13,18,19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-13,18,19,24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/01/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Amendment filed 07/01/2008 is acknowledged. Claims 10, 17,20 are canceled.
Claims 8,9,11-13,18,19,21-25 are currently pending.
Claims 11-13, 18,19,24,25 remain withdrawn from consideration.

With respect to claim 21 submitted in amendment filed 11/21/2007, applicant's arguments are deemed persuasive-in-part. Examiner agrees that the second compound of the claim is within the scope of the base claim 8; however, the first compound does not have a C1-C6 group bearing imidazoline group, as addressed in the genus of claim 8. To the extent of this compound, claim 21 is not a proper dependent from claim 7. Said first compound is withdrawn from consideration.

2. Rejections not reiterated from previous Office actions are hereby withdrawn. Amendment to claim 8 limiting the scope to imidazolidine substitute (instead of a "hydrogen bond accepting group", and nitrogen-containing heterocyclic group as elected species) obviates rejections of claims 8,22,23.

As claims 8,22,23 are allowable, examination was proceeded to species of claim 9 (now independent claim) directed to C4-5 alkyl group bearing a keto group derivative.

Claim Objections

3. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim: the first compound does not have a C1-C6 group bearing imidazoline group, as addressed in the genus of claim 8. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Priority

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

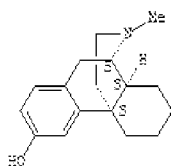
The disclosure of the prior-filed application, Application No. 10/411206, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The disclosure of 10/411206, while disclosing a vaguely defined genus of potential structure of putative inhibitors does not disclose particular compounds as instantly claimed.

Thus, the effective priority date of filing of 10/411206 is not granted. The effective priority date of the instant application is its filing date, 04/09/2004.

Claim Rejections - 35 USC § 103.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as obvious over Wu et al (US 20050107415; priority date 11/07/2003)¹.

The claim is directed to dextromethorphan derivative having methyl group substituted with C4-5 alkyl group bearing a keto- group . Dextromethorphan is a compound of formula



(Registry Number 125-73-5)

Wu et al teach dextromethorphan derivatives of compound RAX, wherein R can be H, A is of formula VII (i.e., a dextromethorphan derivative), X is (CH₂)_n -R₅, R₅ is COR₈, and R₈ can be alkyl. See claim 1. As such, RAX, wherein X is (CH₂)_n -CO-Alkyl reads on the to dextromethorphan derivative having methyl group substituted with C4-5 alkyl group bearing a keto- group as instantly claimed. It would be *prima facie* obvious to one skilled in the art at the time the invention was made to be motivated to combine structural elements of RAX compound disclosed at Wu to obtain functional equivalents having the activity as addressed in the reference.

¹ See also Wu et al, US 20050261329, paragraph [0040].

Information Disclosure Statement

The information disclosure statement filed 07/01/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Conclusion

5. Claims 8,22,23 are allowed.

Prior art of record does not teach dextromethorphan derivative having methyl group substituted with alkyl group bearing imidazolidine group. Wu et al. (US 20050107415) teach dextromethorphan derivatives of compound RAX, wherein X can be $(CH_2)_n - R_6R_7$, and R6 and R7 can be heterocycles, e.g., imidazolidines. However, this will read on a dextromethorphan derivative having two imidazolidine groups, not one as instantly claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631

mlb